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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/510,378	02/22/2000	Maureen T. Cronin	18547-004131US	3064

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EXAMINER
PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/510,378	Cronin et al
Examiner	**Art Unit**
Padmashri Ponnaluri	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 16, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *59-92* is/are pending in the application.

4a) Of the above, claim(s) *59-81* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *82-92* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

NOTE: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639.

1. The amendment filed on 7/16/02 has been fully considered and entered into the application.

2. Claims 59-92 are currently pending in this application.

3. Applicant's election without traverse of group II, claims 82-92, filed on 1/8/02, in Paper No. 12 is acknowledged.

4. Claims 59-81 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 12.

5. Claims 82-92 are currently being examined in this application.

6. The obviousness-type double patenting rejection of claims 82-92 over US Patents 5,837,832; 5,837,832; and 6,309,823 of record, have been withdrawn in view of filing of terminal disclaimers.

7. The rejection of claims 82-92 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling, set forth in the previous office action has been maintained for the reasons of record.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 82-83, 85-86, 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,700,637 (Southern et al).

Southern teaches apparatus and methods for analyzing polynucleotide sequence and method of generating oligonucleotide. The reference teaches a method for analyzing either an unknown sequence or known sequence (i.e., see abstract). The reference teaches that the disclosed apparatus for analyzing polynucleotide sequence, in one embodiment the apparatus comprises a solid support and attached to a surface an array of whole or chosen part of complete set of oligonucleotide occupying separate cells of the array (refers to first probe set and second probe set of the instant claims) and being capable of taking part in hybridization reactions, for

studying, difference between polynucleotide sequence (i.e., see column 1, lines 36-60). The reference in example 3 teaches that for study of the effects of mismatches or shorter sequence eon hybridization behavior, two arrays: one with 24 oligoncleotides and the other of 72 oligonucleotide was synthesized. The reference table 1(a) and 1(b) shows the two different arrays. The oligonucleotide sequences (or probes) in table 1, have some common or fixed nucleic acid positions in all the probes and specific nucleotide positions are different (refers to the 'at least one interrogation position is occupied by a different nucleotide in each of the two corresponding probes of the instant claims). For example, the reference oligonucleotide sequences in table 1, have at positions 13-15 have different nucleotide (refers to the probe set with at least three interrogation positions of the instant claims).

The claimed invention differs from the prior art teachings by reciting a reference sequence or first probe set or second probe set. The reference teaches several different oligonucleotide array which are used in hybridization assays to analyze known or unknown target oligonucleotide synthesis. The reference has more than one oligonucleotide sequence which occupy separate cells of array, which can be interpreted as different probe sets. And in the absence of recitation of the reference sequence in the instant claims, any one of the sequences in the reference array are considered as reference sequence. Thus, it would have been obvious to one skilled in the art at the time the invention was made to use arrays disclosed by the reference as probe sets, since the reference uses the array of oligonucleotide sequences in determining or analyzing the sequence of the target oligonucleotide sequence.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U. S. P. Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U. S. P. Q. 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 U. S. P. Q. 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 U. S. P. Q. 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

11. Claims 82-92 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-40 of copending Application No. 08/510,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim method exactly same as the reference claims, except the instant claims are broad and open regarding the length of the segment of the probe which is exactly complementary to the reference sequence, whereas the

reference claims specifically recites the length of the sequence of the probe which is exactly complementary to the reference sequence. Thus, the reference claims are obvious over the instant claim method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 82-92 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling (set forth in the previous office action). a) The length of the probe ; and b) reference sequence, is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 U. S. P. Q. 356 (CCPA 1976). The instant claims do not recite the probe length which is critical in hybridization. The probe should be long enough to allow the probe to hybridize to the reference sequence. Thus, it is essential for the invention to include the length of the probes in the array. And the specification teaches that the target sequences differ from the reference sequences at one or more positions but show high sequence identity with the reference sequence. And the references include known mutations or polymorphism associated with phenotypic changes having clinical significance. Thus, the reference sequence is known and should be closely related to the target sequence. Moreover, the reference sequence is a predetermined sequence such that

the array of the probe sets can be prepared which are used in the instant assay. Thus, the information regarding the reference sequence is necessary.

14. Applicant's arguments filed on 7/16/02, regarding the 35 U. S. C. . 112 first paragraph rejection of record have been fully considered but they are not persuasive. .

Applicants argue that it is inherent in the claims that an array should include probes of sufficient length to hybridize to the target sequence, because otherwise there would be no hybridization pattern. Applicants arguments are not persuasive, since the instant claims recite a method of use of the probes in hybridization assays, the length of the probe is critical in these assays, and since applicants point out that different lengths are tested for suitability. That is, the person skilled in the art would require to do undue experimentation in determining the proper length of the probes such that the probes are complementary to the reference sequence and have specific interrogation positions. Applicants have not given enough information regarding the reference sequence or the length of the reference sequence, and in the absence of the reference sequence information, one skilled in the art would not be able to determine the sequence or the length of the probes. And further it seems in the claimed method there seems to be correlation between the reference sequence and the target sequence. Applicants arguments that any sequence can serve as reference sequence is considered and is not persuasive. By using the claimed method of determining the target sequence , the specification discloses that the target sequences differ from the reference sequences at one or more positions but show high sequence identity with the reference sequence, which refers to that the the target sequence and the

reference sequence are closely related. Since in the claimed method, several factors are dependent on the probe sequence, and the reference sequence. Without the knowledge of the reference sequence the probe sequence of the first probe set and the second probe set can not be determined or synthesized. Thus, these are critical and necessary for the claimed invention.

15. Applicant's arguments filed on 6/17/02, regarding the 35 U. S. C. Second paragraph rejection of claims, have been fully considered but they are not persuasive.

A) Claims 82-92 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the length of the probes and information regarding the reference sequence.

Applicants arguments have been considered regarding the length of the probe and reference sequence, but are not persuasive for the reasons discussed supra.

16. Examiner acknowledge applicants submission of relevant applications pending in the office. However, examiner is unable to obtain 09/798,260, to determine whether the claims are obvious over the instantly pending claims. Applicants are requested to provide a copy of claims from 09/798,260.

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1639
31 October 2002

PADMASHRI PONNALURI
PRIMARY EXAMINER